

Remarks

Claims 15, 35, and 43 were amended herein, without prejudice. Claims 16-17 and 34 has been cancelled herein, without prejudice.

Rejection of Claims and Traversal Thereof

In the March 30, 2009 Office Action:

claims 15-17, 34, 35 and 43 were rejected under 35 U.S.C. §112, first paragraph;

claims 34-35 were rejected under 35 U.S.C. §102 (a) and (e) as anticipated by US 6,451,567 (hereinafter Barclay '567);

claim 15 was rejected under 35 U.S.C. §102 (b) as anticipated by Middleditch et al. (*J. Chrom.*, 195 (1980) 359-368) (hereinafter Middleditch);

claim 43 was rejected under 35 U.S.C. §102 (a) and (e) as anticipated by or in the alternative under 35 U.S.C. §103 (a) as obvious over Barclay '567; and

claims 15, 34, 35 and 43 were rejected under 35 U.S.C. §102 (b) and (e) as anticipated by or in the alternative under 35 U.S.C. §103 (a) as obvious over WO 99/06585 (hereinafter Gladue).

These rejections are hereby traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

Rejection under 35 U.S.C. §112, first paragraph

In the March 30, 2009 Office Action, claims 15-17, 34, 35 and 43 were rejected under 35 U.S.C. §112, first paragraph.

Claims 15, 34, 35 and 43 were rejected because the specification, while being enabling for a method of producing shrimp exhibiting a DHA:EPA ratio of greater than 1 comprising feeding shrimp a standard shrimp feed supplemented with *Schizochytrium* sp., does not reasonably provide enablement for the

claimed method or resulting shrimp using other species of microalga. Applicants have amended the pending claims to recite the *Schizochytrium* sp. as the claimed microalgae, thereby obviating these rejections.

Applicants request that the Office reconsider these rejections under section 112 and withdraw same.

Rejection under 35 U.S.C. §102 (a) and (e)

1. In the March 30, 2009 Office Action, claims 34-35 were rejected under 35 U.S.C. §102 (a) and (e) as anticipated by US 6,451,567 (hereinafter Barclay '567). Applicants submit that Barclay '567 does not in anyway anticipate the presently claimed invention.

Claim 35, as amended herein, recites:

35. A method of producing a shrimp exhibiting a DHA/EPA ratio greater than 1, wherein the method comprises feeding to said shrimp one or more components chosen from microalgae enriched with DHA and microalgal extracts enriched with DHA, wherein the microalgae is selected from *Schizochytrium* sp., *Schizochytrium aggregatum*, and *Schizochytrium aggregatum* ATCC 28209.

The Barclay '567 reference does not disclose a shrimp comprising a DHA/EPA ratio greater than 1.0. Notably, Example 12 of Barclay '567 allegedly discloses the feeding of an algae based feed supplemental to artemia followed by the subsequent harvest and fatty acid content analysis. The results were provided in Figures 7 (ATCC 20890) and 8 (ATCC 20888), reproduced hereinbelow for ease of reference.

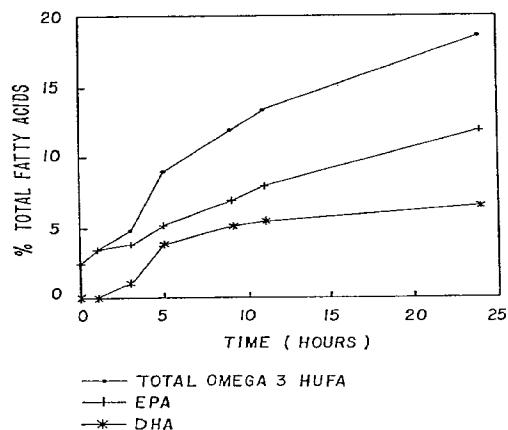


FIG. 7

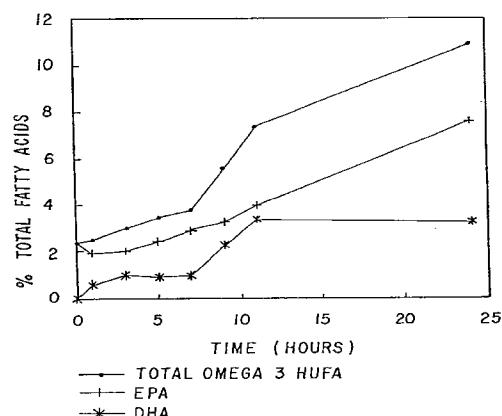


FIG. 8

Clearly, the results shown in Figures 7 and 8 show that the DHA level is much lower than the EPA and as such there is no disclosure of an artemia having a DHA/EPA ratio less than 1.

Applicants need to address the ambiguity of the Barclay '567 reference that is very evident when reviewing the description for Figure 8 and the microflora described therein.

FIG. 8 is a graph of increases in the omega-3 HUFA content of the total lipids in the brine shrimp, *Artemia salina*, fed Thraustochytrid strain (ATCC 20888) isolated by the method in Example 1. EPA=C20:5n-3; DHA=C22:5n-3.

The description states that the inventors used ATCC 20888 which is a Schizochytrium sp as shown below.

The screenshot shows the ATCC website interface. At the top left is the ATCC logo and "The Global Bioresource Center" tagline. To the right is a search bar with "Search Catalog" and "Select a Category" dropdown, and a "Login Search Options" button. Below the header are navigation links: About, Cultures and Products, Science, Standards, Deposit Services, Custom Services, and Product Use Policy. The main content area displays "ATCC Advanced Catalog Search > Product Details" for "Product Description". It includes a note about reading the Material Transfer Agreement before ordering. The product listing for "Fungi, Yeasts and Yeast Genetic Stock" shows ATCC Number 20888™, Organism Schizochytrium sp., Designation S31, Price \$195.00, and links to Related Links and ATCC Biocat Search. A "Print this Page" link is also present.

Or as set forth in the Barclay specification as shown in column 10:

Strain	ATCC No.	Deposit Date
Schizochytrium S31	20888	8/8/88
Schizochytrium S8	20889	8/B/88

Thus it is very evident that the results shown in Figure 8, wherein the DHA:EPA ratio is much less than 1 are the results of using a *Schizochytrium* sp. This is important when discussing what this reference teaches or suggest to a skilled artisan.

Considered *in toto*, the results shown in Figure 8, which correspond to artemia that consumed Schizochytrium sp. cannot anticipate applicants' claimed invention because the artemia clearly have a DHA/EPA ratio less than 1. As such, the Barclay '567 reference does not disclose the presently claimed invention and is not anticipatory. Withdrawal of the rejection is respectfully requested.

2. In the March 30, 2009 Office Action, claim 15 was rejected under 35 U.S.C. §102 (b) as anticipated by Middleditch et al. (*J. Chrom.*, 195 (1980) 359-368) (hereinafter Middleditch). Applicants traverse such rejection.

Claim 15 has been amended to recite:

15. An aquaculturally-raised shrimp comprising a docosahexaenoic acid/eicosapentaenoic acid (DHA/EPA) ratio greater than 1.0, wherein the shrimp were fed one or more components chosen from microalgae enriched with DHA and microalgal extracts enriched with DHA, wherein the microalgae is selected from *Schizochytrium* sp., *Schizochytrium aggregatum*, and *Schizochytrium aggregatum* ATCC 28209.

Middleditch relates to the supplementation of the diet of *Panaeus setiferus* (i.e., white shrimp) with the **bloodworm** *Glycera dibranchiata*. Comparing applicants' claim 15, which relates to shrimp fed one or more components chosen from microalgae enriched with DHA and microalgal extracts enriched with DHA, wherein the microalgae is selected from *Schizochytrium* sp., *Schizochytrium aggregatum*, and *Schizochytrium aggregatum* ATCC 28209, with Middleditch, which relates to shrimp fed *g. dibranchiata*, it can be seen that Middleditch does not anticipate applicants' claim 15. Accordingly, withdrawal of the rejection of claim 15 in view of Middleditch is respectfully requested.

Rejection under 35 U.S.C. §102/103

1. In the March 30, 2009 Office Action, claim 43 was rejected under 35 U.S.C. §102 (a) and (e) as anticipated by or in the alternative under 35 U.S.C. §103 (a) as obvious over Barclay '567. Applicants traverse such rejection.

Claim 43 has been amended herein to recite:

43. A method of feeding a shrimp to a human or non-human animal, comprising providing for the animal's consumption a shrimp, wherein the shrimp were fed one or more components chosen from microalgae enriched with DHA and microalgal extracts enriched with DHA, wherein the microalgae is selected from *Schizochytrium* sp., *Schizochytrium aggregatum*, and *Schizochytrium aggregatum* ATCC 28209 and wherein the shrimp comprises a docosahexaenoic acid/eicosapentaenoic acid (DHA/EPA) ratio greater than 1.0.

Since claim 43 includes the same algal limitations as claim 35, claim 43 is not anticipated by Barclay '567, as discussed hereinabove.

Further, the Barclay '567 reference does not render obvious the presently claimed invention. Initially, the Barclay '567 reference never recognizes the importance of a DHA/EPA ratio greater than one. Additionally, the Barclay '567 reference provides no guidance or suggestion to go in that direction. Instead, the examples suggest that the inclusion of fatty acid in the artemia tissue, wherein the EPA is in a higher amount, is acceptable because there is an overall increase in total omega-3-HUFA, which is the result that Barclay '567 was attempting to achieve.

Most importantly, the Barclay 567 reference teaches away from going in the direction of applicants' claimed invention. Clearly a skilled artisan reviewing the results set forth in Figure 8, knowing that the microflora is a *Schizochytrium* sp would not consider that using such a yeast strain for feeding to shrimp would be successful and increase the level of DHA to cause a DHA:EPA ratio greater than 1.

According to the MPEP §§ 2141.02, prior art must be considered in its entirety, including disclosures that teach away from the claims. Clearly the results set forth in Figure 8, teach away from going in the direction of applicant. Considering the bad results shown in the Barley reference, applicants suggest that the cited reference teaches away from applicants' claimed invention. The Court in *In re Gurley*, 31 USPQ2d 1131 (Fed. Cir. 1994) addressed this very issue and stated:

“[I]n general, a reference will teach away if it suggest that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966) (“known disadvantages in old

devices which would naturally discourage the search for new inventions may be taken into account for determining obviousness.)”

Further, the Court in *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 43 USPQ2d 1294 (Fed. Cir. 1997) provided further insight:

“ It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements....evidence that the combination was not viewed as technically feasible must be considered, for conventional wisdom that a combination should not be made is evidence of unobviousness.”

Surely, anyone skilled in the art reading the Barley reference would be discouraged from going in the direction that applicants have gone.

The Office has already stated, when making the rejection under section 112, that “the state of the art holds that it is unpredictable whether any algae will cause an increase in DHA in shrimp fed the algae and the degree of the increase is also variable.” Thus a skilled artisan looking at the results of Barclay ‘567 would not consider using a *Schizochytrium* sp strain because there is no indication of success.

Applicants again remind the Office that Barclay ‘567 never recognized the importance of the DHA/EPA ratio, and thus, such element was unknown. Therefore, how could a skilled artisan make any modification to the teaching of Barclay ‘567 to arrive at the present invention that possesses such heretofore unknown characteristic? Serendipity is not a valid basis for asserting obviousness.

In light of the above discussion, applicants request that the rejections of claim 43 in view of Barclay ‘567 be withdrawn.

2. In the March 30, 2009 Office Action, claims 15, 34, 35 and 43 were rejected under 35 U.S.C. §102 (b) and (e) as anticipated by or in the alternative under 35 U.S.C. §103 (a) as obvious over WO 99/06585 (hereinafter Gladue). Applicants traverse such rejection.

According to the Examiner:

[Gladue] taught feeding microalga to shrimp to increase DHA content. []
The DHA was then blended with the alga chlorella and used as a feed.
[Gladue] does not teach a shrimp fed the feed would yield a

DHA:EPA>1. However, the methods taught by [Gladue] meet the limitations of the method claims and are substantially the same as those taught in the specification to result in the claimed ration [sic] in the product.”

Applicants vigorously disagree.

As introduced hereinabove, claims 15, 35 and 43 have been amended to recite that “the microalgae is selected from Schizochytrium sp., Schizochytrium aggregatum, and Schizochytrium aggregatum ATCC 28209.” Although Gladue does mention that Schizochytrium species may be used as the microbial cells that are fed to fish larvae, bivalves and crustaceans,¹ the results of Barclay '567, specifically Figure 8 as discussed hereinabove, evidence that Gladue cannot anticipate nor make obvious applicants' claimed invention including the DHA/EPA ratio greater than 1. Specifically, as discussed hereinabove, Barclay '567 disclosed the feeding of Schizochytrium sp. (i.e., ATCC 20888) to shrimp and the results clearly show that the shrimp had a DHA/EPA ratio less than 1. Not only does Barclay '567 not anticipate nor make obvious applicants' claimed invention (for the reasons discussed hereinabove), but Gladue cannot be said to anticipate or make obvious applicants' claimed invention because of the evidence provided in Barclay '567. Again, the Office knows that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. Further, the Office must recognize that inherency requires that the desired event occur each and every time and the Gladue reference, can not meet such requirements in light of the results shown in Figure 8 of Barclay '567.

Accordingly, applicants' claimed invention is novel and non-obvious in view of Gladue. Applicants respectfully request withdrawal of the rejection.

Petition for Extension of Time/Fees Payable

Applicants hereby petition for a two (2) month extension of time, extending the deadline for responding to the March 30, 2009 Office Action from June 30, 2009 to August 30, 2009. The fee of \$245.00 specified in 37 CFR §1.17(a)(1) for such extension is hereby enclosed. The total fee is being paid by Electronic Funds Transfer. Authorization is hereby given to charge any deficiency in applicable fees for this response to Deposit Account No. 13-4365 of Moore & Van Allen PLLC.

¹ it should be noted that there are more than 52,000 species of crustaceans and Gladue never recites that the feed is fed to shrimp *per se*.

Conclusion

Applicant has satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Bertoglio reconsider the patentability of the pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. If any issues remain outstanding incident to the allowance of the application, Examiner Bertoglio is requested to contact the undersigned attorney at (919) 286-8089.

Respectfully submitted,



By: _____

Tristan A. Fuierer
Reg. No. 52,926
Attorney for Applicants
Moore & Van Allen, PLLC
Telephone: (919) 286-8000
Facsimile: (919) 286-8199

APPENDIX A

Taxonomy Browser

Entrez Published Nucleotide Protein Genome Structures PMC Taxonomy Books

Search for: as complete name lock

Display: 8 levels using filter: none

Schizochytrium sp. ATCC 20888

Taxonomy ID: 368446
Inherited blast name: slime nets
Rank: species
Genetic code: Translation table 1 (Standard)
Mitochondrial genetic code: Translation table 1 (Standard)
Other names:
synonym: Schizochytrium sp. ATCC20888

Entrez records	
Database name	Direct links
Nucleotide	4
Protein	3
Taxonomy	1

Lineage (full)
cellular organisms; Eukaryota; stramenopiles; Labyrinthida;
Thraustochytridae; Schizochytrium